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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,213	08/05/2003	David Haffner	GLAUKO.011CP1	6863

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EXAMINER	
DOWE, KATHERINE MARIE	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
12/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/634,213	HAFFNER ET AL.	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7-9,11,27,28,37,53-74 and 76-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7-9,11,27,28,37,53-74, and 76-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the amendment filed August 13, 2009.

2. Claims 5, 7-9, 11, 27, 28, 37, 53-74, and 76-86 are currently pending.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 5, 7-9, 11, 27, 28, 37, 53-74, and 76-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,544,249) in view of Lynch et al. (US 6,464,724) and Paraschac et al. (US 6,050,999). Regarding claims 5, 7-9, 11, 37, and 53-69, 72, 77, 78, and 81-83, Yu et al. disclose the invention substantially as claimed including an instrument and method for delivering an implant for treating an ophthalmic condition. The instrument comprises an elongate body comprising a tube (32) having a cutting edge (40; col 6, ll 56-57), a trocar (36) in the tube having a cutting edge (col 7, ll 10-15) sufficiently sharp to cut through the wall of Schlemm's canal, and a biocompatible implant (10) positioned inside the elongate body with the trocar passing through the lumen of the implant (Fig 2), and an actuator (34) for dispensing the implant. The implant comprises a cutting member and is shaped and sized to convey aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye so as to reduce elevated intraocular pressure (Fig 1). The method of using the device comprises inserting the instrument into the eye through an incision (Figs 3-8) and delivering the implant through a wall of Schlemm's canal at a first collector channel

location. The cutting member of the trocar (36) pierces eye tissue and the implant (10) is advanced over the trocar to the first location through a trabecular meshwork of the eye (Figs 5-6).

However, Yu et al. does not disclose the method comprises delivering a plurality of implants. Lynch et al. disclose a similar method for treating an ocular disorder including inserting an instrument into an eye through an incision, utilizing the instrument to deliver a first implant (100) through a wall of Schlemm's canal (30) at a first location, and utilizing the instrument to deliver a second implant (100) through a wall of Schlemm's canal at a second location (Figure 5; col 6, ll 41-50). Lynch et al. teach the locations are at collector channels (55). When implanted, the implants convey aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye (col 4, ll 57-63). Specifically, Lynch et al. teach, "placement of multiple stents [implants] within Schlemm's canal can result in near circumferential traverse of Schlemm's canal" (col 6, ll 45-46). Multiple implants improve the effect of a single implant. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Yu et al. such that multiple implants were delivered, without removing the instrument from the eye between deliveries. Such a modification would create additional flow channels and improve the flow of aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye, thereby further reducing intraocular pressure in more severe cases. Furthermore, Paraschac et al. discloses a device for delivering a plurality of ocular implants (40), wherein the implants are arranged end to end within an elongate tubular member (Fig 9C) and the

actuator (61) comprises a separator (59) to serially dispense the implants in a controlled manner (col 6, ll 45-61). Therefore, it would have been obvious to modify the combination of Yu et al. and Lynch et al. such that the multiple implants were arranged end to end within the tube to be dispensed serially by the actuator in a controlled manner.

Regarding claims 27 and 70, it is old and well known in the art to use imaging techniques throughout surgical procedures to identify target locations and monitor the placement of devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the locations of the implants were determined by imaging collector channel locations.

Regarding claims 28 and 73, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that first and second implants were spaced at least 20 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215). Furthermore, it would have been obvious to try placing the first and second implants at least 20 degrees apart since it is obvious to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success.

Regarding claim 71, it is old and well known in the art to use a superiorly located limbal incision to access the eye in ocular surgeries. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the a superiorly located limbal incision was made to deliver the implants, as ocular surgeons are familiar with the surgical technique for such an incision and the technique is known to be safe and effective.

Regarding claims 74, 76, 79, and 84, Yu et al. do not disclose the implant is placed is in the uveal scleral outflow path of the eye. Lynch et al. teach aqueous humor is normally drained out of the eye through two different routes: “In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for approximately ten percent of the aqueous outflow in humans. The primary pathway for aqueous outflow in humans is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal” (col 1, ll 35-48). Therefore, it would have been obvious to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the first and second locations were in the uveal scleral outflow path of the eye as the uveal scleral outflow path of the eye is a well known normal anatomical drainage location and is a known alternative to the trabecular meshwork outflow path of the eye if the implant is unable to be implanted through the trabecular meshwork in a particular patient.

Regarding claims 80, 85, and 86, Yu et al. does not disclose the implant comprises a therapeutic drug. However, Yu et al. does disclose it is preferable to coat the implant with biological cells to reduce rejection effects and minimize the tendency for fibroblast proliferation, which has the potential to occlude the pathway of the implant. Furthermore, it is old and well known in the art to coat implantable devices with a

therapeutic drug to reduce fibroblast proliferation and reduce rejection effects. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the implants were coated with a therapeutic drug to reduce fibroblast proliferation about the implant.

Response to Arguments

5. Applicant's arguments filed August 13, 2009 have been fully considered but they are not persuasive.

6. Applicant argues Yu teaches away from implanting multiple implants since Yu teaches a single implant will achieve the objective of draining excess aqueous humor from an eye to lower intraocular pressure (IOP) and notes the importance of preventing over-drainage of the aqueous humor. The Examiner respectfully disagrees. While Yu teaches over-drainage is not desired, Yu does not specifically teach that multiple implants will create over-drainage. The amount of drainage that qualifies as "excessive drainage" varies from patient to patient. For example, in a patient that requires more drainage than is normally required to sufficiently reduce IOP, two implants may function to provide the required drainage without over-draining that patient's aqueous humor.

7. In response to applicant's argument that there is no suggestion to combine the references of Yu, Lynch, and Paraschac, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lynch teaches multiple implants improve the effect of a single implant and Paraschac teaches a method of delivering multiple implants in an end to end configuration. Thus, in view of the teachings of Lynch and Paraschac, it would have been obvious to duplicate the implant of Yu and deliver at least two anchors to increase the drainage effect of the single implant method. The examiner additionally notes the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe

December 16, 2009

/K. M. D./
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734